THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF MISSISSIPPI
~~NORTHERN~~ DIVISION
WESTERN

SOUTHWEST MISSISSIPPI REGIONAL MEDICAL CENTER; INFIRMARY HEALTH HOSPITALS, INC., a corporation; MONROE COUNTY HEALTHCARE AUTHORITY, a corporation, d/b/a MONROE COUNTY HOSPITAL, a corporation; on behalf of themselves and all others similarly situated,

Plaintiffs,

AMERISOURCEBERGEN DRUG CORPORATION, CARDINAL HEALTH, INC., McKESSON CORPORATION, PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; NORAMCO, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; ALLERGAN PLC f/k/a ACTAVIS PLS; WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; MALLINCKRODT PLC and MALLINCKRODT LLC.,

Defendants.

CASE NO.: 5:17-CV-145-KS-MTP

RICO STATEMENT

Plaintiffs Infirmary Health Hospitals, Inc., Monroe County Healthcare Authority, d/b/a Monroe County Hospital and Southwest Mississippi Regional Medical Center (collectively, "Plaintiffs"), through undersigned counsel, pursuant to L.R. 83.8, respectfully submit this "RICO Statement."

(1) State whether the alleged unlawful conduct is in violation of 18 U.S.C. §§ 1962(a), (b), (c), and/or (d).

Plaintiffs have alleged:

(a) Violations of § 1962(c) in Count I of the Complaint; and
(b) Violations of § 1962(d) in Count II of the Complaint.

(2) List each Defendant and state the alleged misconduct and basis of liability of each Defendant.

(a) The "Pharmaceutical Manufacturer Defendants":

Purdue Pharma L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Teva Pharmaceutical Industries, LTD.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica Inc. n/k/a Janssen Pharmaceuticals, Inc.; Noramco, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Allergan PLC f/k/a Actavis PLS; Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc.; Watson Laboratories, Inc.; Actavis, LLC;

(b) The "Distributor Defendants":

McKesson Corporation; Cardinal Health, Inc.; and AmerisourceBergen Drug Corporation. The Pharmaceutical Manufacturer Defendants and the Distributor Defendants are collectively referred to herein as "Defendants."

(c) The Alleged Conduct:

Plaintiffs allege the same course of misconduct as to each Defendant. The Defendants operated as an association-in-fact enterprise, and/or utilized a legal entity described below, for the purpose of unlawfully increasing sales, revenues and profits by disregarding their statutory duty to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market, in order to unlawfully increase the quotas set by the DEA and allow them to collectively benefit

from the unlawful formation of a greater pool of prescription opioids from which to profit (the "Opioid Diversion Enterprise").

(3) List the alleged wrongdoers, other than the Defendant(s) listed above, and state the alleged misconduct of each wrongdoer.

Plaintiffs have not alleged that there are wrongdoers other than the Defendants, although the proof may ultimately demonstrate otherwise. Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in the Complaint, may have contributed to and/or participated in the scheme with the Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the Defendants

(4) List the alleged victims and state how each victim was allegedly injured.

Plaintiffs interpret this question as seeking the identification of those victims who are seeking redress in this action. This action is brought by two hospitals, individually and on behalf of a putative class of similarly situated hospitals. Hospitals were damaged by the alleged misconduct by incurring costs arising from the unreimbursed or only partially reimbursed treatment of opioid users and persons harmed by opioid users. Persons other than hospitals were also likely injured by the Defendants' misconduct.

(5) Describe in detail the pattern of racketeering activity or collection of unlawful debts alleged for each RICO claim. A description of the pattern of racketeering must include the following information:

(A) List the alleged predicate acts and the specific statutes which were allegedly violated;

Plaintiffs allege a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud), and violations of 21 U.S.C. § 483(a)(4) (concerning distribution of certain controlled substances).

(B – first clause) Provide the dates of the predicate acts,

Plaintiffs describe predicate acts dating back at least to 2000, and allege that the Enterprises have been operating for at least ten years. Plaintiffs allege that the predicate acts are ongoing as of this date.

(B – second clause) the participants in the predicate acts, and a description of the facts surrounding the predicate acts; and (C) If the RICO claim is based on the predicate offenses of wire fraud, mail fraud, or fraud in the sale of securities, the "circumstances constituting fraud or mistake shall be stated with particularity." FED. R. CIV. P. 9(b). Identify the time, place, and contents of the alleged

misrepresentations, and the identity of persons to whom and by whom the alleged misrepresentations were made;

(1) Acts of mail and wire fraud: The Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market. Acts of mail and wire fraud included the transmission of:

a. The prescription opioids themselves (all Defendants);

b. Documents and communications that facilitated the manufacture, purchase and unlawful sale of prescription opioids (all Defendants);

c. Defendants' DEA registrations (all Defendants);

d. Documents and communications that supported and/or facilitated Defendants' DEA registrations (all Defendants);

e. Documents and communications that supported and/or facilitated the Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas (all Defendants);

f. Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827 (all Defendants);

g. Documents and communications related to the Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74 (all Defendants);

h. Documents intended to facilitate the manufacture and distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence (all Defendants);

i. Documents for processing and receiving payment for prescription opioids (all Defendants);

j. Payments from the Distributors to the Manufacturers (all Defendants);

k. Rebates and chargebacks from the Manufacturers to the Distributors (all Defendants);

l. Payments to Defendants' lobbyists through the Pain Care Forum (all Defendants);

m. Payments to Defendants' trade organizations, like the HDA, for memberships and/or sponsorships (all Defendants);

n. Deposits of proceeds from Defendants' manufacture and distribution of prescription opioids (all Defendants); and

o. Other documents and things, including electronic communications (all Defendants).

(2) 21 U.S.C. § 483(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under that subchapter. Here, Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other document required to be filed with the DEA including the Manufacturer Defendants' applications for production quotas. Specifically, the Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

(D) State whether there has been a criminal conviction for violation of the predicate acts;

Plaintiffs are not aware of any criminal convictions of the named Defendants for violation of the predicate acts. But many persons not named as defendants have been convicted of crimes related, directly or indirectly, to opioids manufactured by, and/or distributed by, the Defendants.

(E) State whether civil litigation has resulted in a judgment in regard

to the predicate acts;

There have been many civil, enforcement and/or administrative proceedings that might be characterized as "civil litigation" involving the Defendants and relating to the predicate acts. These include but are not necessarily limited to:

1. The RICO Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012[1] and 117 recommended decision in registrant actions from The Office of Administrative Law Judges. These numbers include 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.[2] These actions include the following:

   i. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;
   ii. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;
   iii. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;
   iv. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;
   v. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

[1] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.

[2] *Id.*

vi. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

vii. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

viii. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone;

ix. On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and

x. On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a $150,000,000 civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Santa Fe Springs CA, Washington Courthouse OH and West Sacramento CA

2. On April 23, 2015, McKesson filed a Form-8-K announcing a settlement with the DEA and DOJ wherein it admitted to violating the CSA and agreed to pay $150 million and have some of its DEA registrations suspended on a staggered basis. The settlement was finalized on January 17, 2017.[3]

[3] McKesson, McKesson Finalizes Settlement with U.S. Department of Justice and U.S. Drug Enforcement Administration to Resolve Past Claims, About McKesson / Newsroom / Press Releases, (January 17, 2017(), http://www.mckesson.com/about-mckesson/newsroom/press-releases/2017/mckesson-finalizes-settlement-with-doj- and-dea-to-resolve-past-claims/.

3. , Mallinckrodt was recently the subject of a DEA and Senate investigation for its opioid practices. Specifically, in 2011, the DEA targeted Mallinckrodt arguing that it ignored its responsibility to report suspicious orders as 500 million of its pills ended up in Florida between 2008 and 2012.[4] After six years of DEA investigation, Mallinckrodt agreed to a settlement involving a $35 million fine. Federal prosecutors summarized the case by saying that Mallinckrodt's response was that everyone knew what was going on in Florida but they had no duty to report it.[5]

(F) Describe how the predicate acts form a "pattern of racketeering activity"; and (G) State whether the alleged predicate acts relate to each other as part of a common plan. If so, describe in detail.

The predicate acts constitute a pattern of racketeering activity, that involves a fraudulent scheme to increase revenue by violating State and Federal laws requiring the maintenance of effective controls against diversion of prescription opioids, and the identification, investigation, and reporting of suspicious orders of prescription opioids destined for the illicit drug market. The goal of Defendants' scheme was to increase profits from opioid sales. But, Defendants' profits were limited by the production quotas set by the DEA, so the Defendants refused to identify, investigate and/or report suspicious orders of their prescription opioids being diverted into the illicit drug market. The end result of this strategy was to increase and maintain artificially high production quotas of opioids so that there was a larger pool of opioids for Defendants to manufacture and distribute for public consumption.

(6) Describe in detail the alleged enterprise for each RICO claim. A description of each enterprise must include the following information:

(A) State the names of the individuals, partnerships, corporations, associations, or other legal entities which allegedly constitute the enterprise;

Plaintiffs have alleged, in the alternative, that the Defendants carried out their illegal activity through: (1) an association-in-fact enterprise (the "AIF") between the Manufacturer Defendants and the Distributor Defendants, Complaint, ¶ 252, and (2) that

[4] Lenny Bernstein & Scott Higham, The government's struggle to hold opioid manufacturers accountable, The Washington Post, (April 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.b24cc81cc356. This number accounted for 66% of all oxycodone sold in the state of Florida during that time.

[5] *Id.*

the Defendants carried out their illegal activity through the Healthcare Distribution Alliance (the "HDA")[6] (the HDA and the AIF are collectively referred to as the "Enterprises") *Id.*, ¶ 263

(B) Describe the structure, purpose, function, and course of conduct of the enterprise;

The AIF is an enterprise in fact whose sole purpose is to engage in the racketeering activity described in the Complaint.

The HDA is a trade organization representing pharmaceutical distributors. The HDA is a distinct legal entity that is a non-profit corporation formed under the laws of the District of Columbia and doing business in Virginia as a non-profit corporation. The HDA was used by the Defendants to conduct their pattern of racketeering activity, but likely performs other functions as a trade organization.

(C) State whether any Defendants are employees, officers, or directors of the alleged enterprise;

The AIF, as an enterprise-in-fact, does not have formal employees, officers or directors.

Plaintiffs have alleged that the Defendants are members of the HDA. Plaintiffs have not alleged whether or not any Defendants are employees, officers or directors of the HDA.

(D) State whether any Defendants are associated with the alleged enterprise;

All Defendants are alleged to be associated with the Enterprises.

(E) State whether the Plaintiffs are alleging that the Defendants are individuals or entities separate from the alleged enterprise, or that the Defendants are the enterprise itself, or are members of the enterprise; and,

Plaintiffs allege that the Defendants are entities separate from the alleged Enterprises, but that they are all members of both Enterprises.

(F) If any Defendants are alleged to be either the enterprise itself or members of the enterprise, explain whether such Defendants are perpetrators, passive instruments, or victims of the alleged racketeering activity.

[6] Health Distribution Alliance, History, Health Distribution Alliance, (last accessed on September 15, 2017), https://www.healthcaredistribution.org/about/hda-history.

Those Defendants who are members of the Enterprises are alleged to be perpetrators of the alleged racketeering activity.

(7) State whether the Plaintiffs are alleging that the pattern of racketeering activity and the enterprise are separate or have merged into one entity. In either event, describe in detail, and (8) Describe the alleged relationship between the activities of the enterprise and the pattern of racketeering activity. Discuss how the racketeering activity differs from the usual and daily activities of the enterprise, if at all.

The purpose of the AIF is to engage in the unlawful sales of opioids, and deceive the public and federal and state regulators into believing that the RICO Defendants were faithfully fulfilling their statutory obligations. The racketeering activity does not differ from, and is, the usual activity of the AIF.

The HDA was utilized by the Defendants to conduct the Opioid Diversion Enterprise and to engage in the pattern of racketeering activity alleged in this action. The racketeering activities were closely related to the usual activities of the HDA, as its general function is to promote the collective financial interests of the pharmaceutical industry, which includes making it easier to manufacture and distribute larger quantities of opioids. The HDA likely also performed other functions and engaged in other activities unrelated to the racketeering activities alleged herein.

(9) Describe what benefits, if any, the alleged enterprise receives from the alleged pattern of racketeering.

The Enterprises themselves are not alleged to benefit from the pattern of racketeering, other than the HDA having more robust sources of funding from its membership. But the Defendants, who are members of the Enterprises, have benefited from increased profits from the manufacture, sale and distribution of opioids.

(10) Describe the effect of the activities of the enterprise on interstate or foreign commerce.

The distribution of opioids is an enterprise that is national in scope. Opioids were placed by the Defendants into the stream of commerce. Revenues derived from the interstate distribution of opioids accrued to the Defendants.

(11) If the complaint alleges a violation of 18 U.S.C. § 1962(a), provide the following information: (A) State who received the income derived from the pattern of racketeering activity or through the collection of an unlawful debt; and, (B) Describe the use, investment, or locus of such income.

Not applicable.

(12) If the Complaint alleges a violation of 18 U.S.C. § 1962(b), describe in detail the acquisition or maintenance of any interest in or control of the

alleged enterprise.

Not applicable.

(13) If the Complaint alleges a violation of 18 U.S.C. § 1962(c), provide the following information:

(A) State who is employed by or associated with the enterprise; and

All of the Defendants are alleged to have been associated with the Enterprises.

(B) State whether the same entity is both the liable "person" and the "enterprise" under § 1962(c).

Neither of the alleged Enterprises is a person alleged to be liable.

(14) If the Complaint alleges a violation of 18 U.S.C. § 1962(d), describe in detail the alleged conspiracy.

In addition to committing distinct predicate acts, the Defendants entered an agreement to, collectively, through the Enterprises, to increase and maintain artificially high production quotas of opioids so that there was a larger pool of opioids for Defendants to manufacture and distribute for public consumption. As part of this agreement, all Defendants agreed to support a goal of increasing and maintaining high production quotas of opioids, and to commit predicate acts, through the Enterprises and otherwise, in pursuit of this objective.

(15) Describe the direct causal relationship between the alleged injury and the violation of the RICO statute.

The Defendants engaged in a racketeering enterprise designed to enable them to produce and distribute larger quantities of opioids than would have otherwise been possible. This exacerbated the national opioid crisis, causing more people to take opioids. This resulted in hospitals having to treat these persons and persons affected by their opioid use, many of whom were uninsured and/or underinsured. As a result, hospitals have incurred substantial costs.

(16) List the actual damages for which Defendant is allegedly liable.

Plaintiffs have not, to date, prepared an estimate of their damages. The damages consist of costs incurred as a result of having to treat patients harmed by opioids and/or opioid users without reimbursement and/or with only partial reimbursement.

(17) List all other federal causes of action, if any, and provide citations to the relevant statute(s).

Not applicable – Plaintiffs do not assert any federal claims other than RICO claims.

(18) List all pendent state claims, if any.

(a) Count III – Negligence
(b) Count IV - Wantonness, Recklessness, And Gross Negligence
(c) Count V – Common Law Fraud

(19) Provide any additional information that you feel would be helpful to the Court in considering your RICO claim

The United States is in the midst of an opioid epidemic caused by Defendants' unlawful marketing, sales, and distribution of prescription opioids that has resulted in addiction, criminal activity, serious health issues, and loss of life. The Manufacturer Defendants aggressively pushed highly addictive, dangerous opioids, falsely representing to doctors that patients would only rarely succumb to drug addiction. These pharmaceutical companies aggressively advertised to and persuaded doctors to prescribe highly addictive, dangerous opioids, and turned patients into drug addicts for their own corporate profit. Such actions were unlawful. The Distributor Defendants, too, along with the Manufacturer Defendants, unlawfully breached their legal duties under federal law to monitor, detect, investigate, refuse, and report suspicious orders of prescription opiates. In this action, Plaintiffs, two hospitals, seek to recover, from the perpetrators of this crisis, at least some of the costs they and their peers (a class of similarly situated hospitals) have borne in responding on the "front lines" of the crisis.

Respectfully Submitted,

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